TRANSMITTAL LETTER TO THE UNITED STATES

FORM PTO-1390 (REV. 5-93)

DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTORNEY'S DOCKET NUMBER

5860

U.S. APPLICATION NO.

CONCERNING & FILE	070702925	
TIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED

INTE	RNAT	IONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/FR96/01346			September 4, 1996	September 5, 1995
TITL	E OF	INVENTION		
		umen Catheter Particul	arly For Hemodialysis	
		T(\$) FOR DO/EO/U\$		
T	nie	rry Pourchez		
Appl	ican	t herewith submits to the Unit	ed States Designated/Elected Office (DO/EO/US) the fol	lowing items and other information.
1.	K	This is a FIRST submission of	items concerning a filing under 35 U.S.C. 371.	
2.		This is a SECOND or SUBSEQUEN	T submission of items concerning a filing under 35 U.S	3.c. 371.
3.		This express request to begin examination until the expirat	national examination procedures (35 U.S.C. 371(F)) at ion of the applicable time limit set in 35 U.S.C. 371(any time rather than delay b) and PCT Articles 22 and 39(l).
4.		A proper Demand for Internati date.	onal Preliminary Examination was made by the 19th mont	h from the earliest claimed priority
5.	K	A copy of the International A	pplication as filed (35 U.S.C. 371(c)(2)):	
.d 14		a. 🔯 is transmitted herewi	th (required only if not transmitted by the Internatio	nal Bureau).
J		b. 🗵 has been transmitted	by the International Bureau.	
1 7 2		c. is not required, as t	he application was filed in the United States Receivin	g Office (RO/US).
6.	KZ	A translation of the Internat	ional Application into English (35 U.S.C. 371(c)(2)).	
7.		Amendments to the claims of the	he International Application under PCT Article 19 (35)	u.s.c. 371(c)(3)):
		a. are transmitted herew	ith (required only if not transmitted by the Internation	onal Bureau).
2		b. have been transmitted	by the International Bureau.	
:		c. have not been made; he	owever, the time limit for making such amendments has	NOT expir ed.
		d. have not been made and	d will not be made.	
8.		A translation of the amendment	ts to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9.		An oath or declaration of the	inventor(s) (35 U.S.C. 371(c)(4)).	
10.		A translation of the annexes (35 U.S.C. 371(c)(5)).	to the International Preliminary Examination Report Unc	der PCT Article 36
Item	s 11	. to 16. below concern other d	ocument(s) or information included:	
11.	[3]	An Information Disclosure Stat	tement Under 37 CFR 1.97 and 1.98	
12.		An assignment document for rec	cording. A separate cover sheet in compliance with 37	CFR 3.28 and 3.31 is included.
13.	X	A FIRST preliminary amendment.		
		A SECOND or SUBSEQUENT prelimi	nary amendment.	
14.		A substitute specification.		
15.		A change of power of attorney	and/or address letter.	
16.	M	Other items or information: Verified Statement (D	eclaration) Claiming Small Entity Stat	us (37CFR 1.9(f) and

1.27(b) - Independent Inventor

Information Disclosure References

U.S. APPLICATION NO. (1f known, see 37 C.F.R. 1.50)		INTERNAT	INTERNATIONAL APPLICATION NO.		ATTORNEY DOCKET NO.		
(IT KIIOMI, See 37 C.		PCT/FR	PCT/FR96/01346			5860	
17. The following fees are submitted:					CALCULATIONS	PTO USE ONLY	
Basic Nation - Search Report							
International p	oreliminary examinatio	n fee paid	to USPTO (37 CFR 1.48	2)\$ 720.00			
	al preliminary examina nal search fee paid to						
Weither international s	ational preliminary ex search fee (37 CFR 1.4	amination 45(a)(2))	fee (37 CFR 1.482), no paid to USPTO	\$1070.00			
International pand all claims	oreliminary examination satisfied provisions of	n fee paid of PCT Art	to USPTO (37 CFR 1.48 icle 33(2)-(4)	2) \$ 98.00			
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Claims	Number Filed		Number Extra	Rate	***************************************		
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			TOTAL NATION	AL FEE =	s 465.00		
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overpayment to	ner is hereby authorize Deposit Account No. 1	11-0610.	I duplicate copy of the	is sheet is enclosed	d. `	•	
OTE: Where an approp .137(a) or (b)] must	oriate time limit under be filed and granted t	r 37 CFR 1. to restore	.494 or 1.495 has not I the application to per	been met, a petition nding status.	n to revive [37 C	FR	
END ALL CORRESPONDENC	E TO:			AlluC	Lew		
John C. Kerins,				SIGNATURE	<u> </u>		
Kerkam, Stowell	, Kondracki & Cl	arke P.	С.	John C. Ker	ins		
5203 Leesburg Pr Falls Church, V				32,421 REGISTRATION NO.			
				ACGISTRATION NO.			

Docket: 5860

IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

Applicant:

Thierry POURCHEZ

International

Application No.:

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PCT/FR96/01346

International

Filing Date:

September 4, 1996

U.S. Serial No.:

To Be Assigned

U.S. Filing Date:

March 5, 1998

For: Multilumen Catheter Particularly For Hemodialysis

Falls Church, Virginia March 5, 1998

PRELIMINARY AMENDMENT

Honorable Commissioner of Patents and Trademarks Washington, D.C. 20231

Sir:

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This Preliminary Amendment is filed concurrently with the filing of a Request for entry into national stage examination of the subject patent application. Please amend the application as indicated below.

IN THE SPECIFICATION:

At page 1, after the title of the invention, please insert the following headings:

- --BACKGROUND OF THE INVENTION
- 1. Field of the Invention--.

Page 1, before line 9, please insert the following heading:

-- 2. Description of Related Art--.

Page 1, before line 27, please insert the following heading:

--SUMMARY OF THE INVENTION--.

Page 2, before line 6, please insert the following heading:

-- BRIEF DESCRIPTION OF THE DRAWING--.

Page 2, line 8, after "drawing", delete ", which represents a", and replace with --.--

Page 2, line 9, before "side", please insert --FIG. 1 is a--.

Page 2, before line 11, please insert the following heading:

--DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT--.

IN THE CLAIMS:

- 1. (Amended) A multilumen catheter (1) [of a
- 2 type] comprising:
- 3 at least two inner lumens (2, 3), defined
- by a wall (2A, 3A), each of [which is intended for
- 5 guiding] said inner lumens being adapted to guide at
- 6 least one fluid (4),
- 7 two opposite ends (5, 6), <u>a first</u> one of
- 8 which (5) is [called] a distal end, [since it is] said
- 9 <u>distal end</u> specifically intended to be placed in a cavity

10	of a patient's body [(not represented) in order] and
11	<pre>adapted to deliver and/or sample the fluid (4) to or from</pre>
12	[it] said distal end through at least one channel (7, 8),
13	[the other] a second end (6) being [called] a proximal
14	end, [since it is specifically intended] said proximal
15	end adapted to be connected to a means (9) for
16	circulating fluid (4), [such as a fluid perfusing and/or
17	extracting means,]
18	[this catheter being characterized in that,
19	in order to constitute its] said distal end of said
20	catheter, [it comprises beyond a so-called] having a
21	dividing point (12) located at a predetermined distance
22	D1 from [its] <u>said</u> proximal end (6), <u>and having</u> at least
23	two distinct elongated end portions (13, 14) extending
24	from said dividing point [which:]
25	[-] wherein said at least two end portions,
26	in at least one rest position of the catheter, extend
27	substantially parallel to [the] \underline{a} longitudinal axis of
28	[this] said catheter, each over a predetermined length
29	(L1, L2) measurable between a free end of said distal end
30	(13A, 14A) and the dividing point (12),
31	[-] wherein said at least two end portions
32	are each made of flexible material so as to be flexible
33	at least under the effect of a lateral action due to the
34	displacement of a fluid, and
35	[- contain] wherein each of said at least

two end portions contains at least one segment of at

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37	least one of the lumens (2, 3) and [have] has at least
38	one channel (7, 8) for delivering and/or sampling the
39	fluid.

1	2. (Amended) The <u>multilumen</u> Catheter
2	according to claim 1, [characterized in that] wherein:
3	- [the] each of said at least two end
4	portions [have] has a different [lengths] length (L1,
5	L2), and
6	- the channels with which [these] <u>each of</u>
7	said at least two end portions are equipped are [disposed
8	so that each of them] so constructed and arranged such
9	that each emerges at a different [level of] position
LO	along the catheter.

3. (Amended) The <u>multilumen</u> catheter according to claim 2, [characterized in that] <u>wherein</u> the channels with which the <u>at least two</u> end portions are equipped are disposed in a group on each end portion, and [these] <u>wherein said</u> groups are disposed at different [levels of] <u>positions along</u> the catheter.

REMARKS

This Preliminary Amendment is filed to add appropriate headings in the specification to conform the specification to U.S. standards, and to amend the claims

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to bring the claims into a format more familiar to U.S. practice.

Early and favorable consideration on the merits of this application is respectfully requested.

Respectfully submitted,

KERKAM, STOWELL, KONDRACKI & CLARKE, P.C.

John C. Kerins Reg. No. 32,421

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MULTILUMEN CATHETER, PARTICULARLY FOR HEMODIALYSIS

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The invention relates to a device called a multilumen catheter, used for the circulation of a least one fluid between a cavity of a patient's body and a means for circulating this fluid such as a fluid perfusing and/or extracting means.

The invention relates more particularly, though not exclusively, to a catheter for hemodialysis.

The term multilumen catheter designates a catheter comprising at least two inner lumens defined by a wall, each of which is intended for guiding at least one fluid.

A catheter of this type also comprises two opposite ends, one of which is called a distal end since it is specifically intended to be placed in a cavity of a patient's body in order to deliver and/or sample the fluid to or from it through at least one channel, the other being called a proximal end, since it is specifically intended to be connected to a fluid circulating means such as a fluid perfusing and/or extracting means.

With the known catheters, the risk of clogging substances being deposited on the surfaces of the perfusing and/or extracting channels is substantial.

One object of the invention is to obtain a catheter having a risk of obstruction by clogging that is substantially reduced relative to the known catheters.

To this end, the subject of the invention is a catheter of the above-mentioned type, this catheter being characterized in that in order to constitute its distal end, it comprises, beyond a so-called dividing point located at a predetermined distance from its proximal end, at least two distinct elongated end portions which:

- in at least one rest position of the catheter, extend substantially parallel to the longitudinal axis of this catheter, each over a predetermined length measurable between a free end and the dividing point,
 - are each made of flexible material so as to be

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flexible at least under the effect of a lateral action due to the displacement of a fluid,

- contain at least one segment of at least one of the lumens and have at least one channel for delivering and/or sampling the fluid.

The invention will be clearly understood by reading the following description given as a non-limiting example in reference to the appended drawing, which represents a side view of one embodiment of a catheter according to the invention.

The drawing shows an elongated device called a catheter 1 comprising:

- at least two inner lumens 2, 3, defined by a wall 2A, 3A, each of which is intended for guiding at least one fluid 3,

- two opposite ends 5, 6, one of which 5 is called a distal end, since it is specifically intended to be placed inside a cavity of a patient's body (not represented) in order to deliver and/or sample the fluid 4 to or from it through at least one channel 7, 8, the other end 6 being called the proximal end, since it is specifically intended to be connected to a means 9 for circulating a fluid 4, such as a fluid perfusing and/or extracting means.

The fluid 4 is represented by arrows 4.

As shown, the channels 7, 8 are comprised of perforations disposed in the wall of the catheter that defines each of the lumens 2, 3.

These channels allow either the delivery into the area surrounding the catheter of a fluid contained in a lumen of this catheter, or the entry into a lumen of this catheter of a surrounding fluid.

For example, at least one of the lumens is intended for perfusing a fluid and at least one other lumen is intended for extracting fluid.

Also as shown, the lumens 2, 3 for circulating the fluid 4 are for example comprised of juxtaposed lumens,

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but this is not limiting for the invention.

The dimensions and proportions of the catheter represented are not limiting for the invention.

At its proximal end 6, the catheter has elements 10, 11 for connecting each of the lumens 2, 3 it comprises to the means 9 for circulating fluid 4.

As neither the circulating means 9 nor the elements 10, 11 for connecting to this means 9 are subjects of the invention, these elements 10, 11 and the means 9 are not represented in detail.

It is at the distal end 5 that the catheter of the invention is noteworthy.

In effect, in order to constitute its distal end, the catheter comprises, beyond a so-called dividing point 12 located at a predetermined distance D1 from its proximal end 6, at least two distinct elongated end portions 13, 14 which:

- in at least one rest position of the catheter, extend substantially parallel to the longitudinal axis of this catheter, each over a predetermined length L1, L2 measurable between a free end 13A, 14A, and the dividing point 12,
- are each made of flexible material so as to be flexible at least under the effect of a lateral action due to the displacement of a fluid,
- contain at least one segment of at least one of the lumens 2, 3 and has at least one channel 7, 8 for delivering and/or sampling the fluid.

These technical characteristics, when the distal end of the catheter is placed on the axis of a fluid flow such as a bodily fluid flow, allow the end portions, due to their flexibility and independence, to act like a sail set parallel to the wind and thus are practically not subject to obstruction.

In effect, the agitation and flexion of these end portions considerably reduces the risk of clogging substances being deposited on the surfaces of the

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perfusing and/or extracting channels with which these end portions are equipped.

According to another noteworthy characteristic, the end portions have different lengths L1, L2, and the channels with which these end portions are equipped are disposed so that each of them emerges at a different level of the catheter.

According to another characteristic of the invention, the channels with which the end portions are equipped are disposed in a group on each end portion, and these groups are disposed at different levels of the catheter.

CLAIMS

- 1 1. A multilumen catheter (1) of a type comprising:
- 2 at least two inner lumens (2, 3), defined by a wall
- 3 (2A, 3A), each of which is intended for guiding at least
- 4 one fluid (4),
- 5 two opposite ends (5, 6), one of which (5) is called
- a distal end, since it is specifically intended to be
- 7 placed in a cavity of a patient's body (not represented)
- 8 in order to deliver and/or sample the fluid (4) to or
- from it through at least one channel (7, 8), the other
- end (6) being called a proximal end, since it is
- specifically intended to be connected to a means (9) for
- 12 circulating fluid (4), such as a fluid perfusing and/or
- 13 extracting means,
- 14 this catheter being characterized in that, in order to
- constitute its distal end, it comprises beyond a so-
- 16 called dividing point (12) located at a predetermined
- distance D1 from its proximal end (6), at least two
- distinct elongated end portions (13, 14) which:
- in at least one rest position of the catheter extend
- substantially parallel to the longitudinal axis of this
- 21 catheter, each over a predetermined length (L1, L2)
- measurable between a free end (13A, 14A) and the dividing
- 23 point (12),
- are each made of flexible material so as to be
- 25 flexible at least under the effect of a lateral action
- 26 due to the displacement of a fluid,
- contain at least one segment of at least one of the
- lumens (2, 3) and have at least one channel (7, 8) for
- 29 delivering and/or sampling the fluid.
 - 1 2. The catheter according to claim 1, characterized in
- 2 that:
- 3 the end portions have different lengths (L1, L2),
- 4 and

- the channels with which these end portions are equipped are disposed so that each of them emerges at a different level of the catheter.
- 3. The catheter according to claim 2, characterized in that the channels with which the end portions are equipped are disposed in a group on each end portion, and these groups are disposed at different levels of the catheter.

ABSTRACT

A multilumen catheter (1) of a type comprising two inner lumens (2, 3) defined by a wall (2A, 3A) for guiding a fluid (4), and two opposite ends (5, 6), namely a distal end (5) and a proximal end (6), characterized in that the distal end is formed of two elongated and discrete end portions (13, 14) located beyond a so-called dividing point (12) at a predetermined distance D1 from the proximal end (6), wherein said end portions, in a rest position of the catheter, extend parallel to the longitudinal axis thereof, each over a predetermined length (L1, L2) measurable between a free end (13A, 14A) and the dividing point (12), are each made of a flexible material, contain a segment of at least one lumen (2, 3) and have at least one channel (7, 8) for delivering and/or sampling the fluid.

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French Language Declaration

POUVOIR: En tant qu'inventeur, je désigne l'(les) avocat(s) et/ou l'(les) agent(s) suivant(s) pour poursuivre la procédure de cette demande et traiter toute affaire la concernant supris du Bureau des Brevets et de Marques:

Harold L. Stowell, Reg. 17,233 Edward J. Kondracki, Reg. 20,604 Dennis P. Clarke, Reg. 22,549 William L. Feeney, Reg. 29,918 John C. Kerins, Reg. 32,421 POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. (list name and registration number)

Harold L. Stowell, Reg. 17,233 Edward J. Kondracki, Reg. 20,604 Dennis P. Clarke, Reg. 22,549 William L. Feeney, Reg. 29,918 John C. Kerins, Reg. 32,421

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Inventor's signature Residence Citizenship	Date
Residence	Date
Citizenship	
Post Office Address	
Full name of second joint inventor, if any	
Second Inventor's signature	Date
Residence	
Citizenship	
Post Office Address	
	Second Inventor's signature Residence Citizenship

(Fournir les mêmes renseignements et la signature de tout ∞ -inventeur supplémentaire.)

(Supply similar information and signature for third and subsequent joint inventors.)

Page 3 of 3

Patent and Trademark Office-U.S. DEPARTMENT OF COMMERCE

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French Language Declaration

Je revendique par le présent acte le bénéfice de priorité étrangère selon Titre 35, du Code des Etats-Unis, §119 de toute demande de brevet ou d'attestation d'inventeur énumérée ci-après, et j'ai identifié également ci-après toute demande étrangère de brevet ou d'attestation d'inventeur ayant une date de dépôt antérieure à celle de la demande pour laquelle la priorité est revendiquée.

I hereby claim foreign priority benefits under Title States Code, §119 of any foreign application(s) for inventor's certificate listed below and have also below any foreign application for patent or inventor cate having a filing date before that of the applica which priority is claimed:

Prior foreign ap	volucations			Priority (claimed
Demande(s) de		<u>Droit de priorité</u> <u>revendiqué</u>			
(Number) (Country) (Numéro) (Pays)			(Day/Month/Year Filed) (Jour/Mois/Année de dépôt)		No Non
(Number) (Numéro)	(Country) (Pays)	(Day/Month/Ye. (Jour/Mois/Ann		Yes Qui	No Non
(Number) (Numéro)	(Country) (Pays)	(Day/Month/Yea (Jour/Mois/Anné		- Yes Oui	No Non
du Code des Eta ricaines énuméré de chacune des divulgué dans la c dèfinie par le pre Etats-Unis, §112, mation pertinente Fédéraux, §1.56 la date de dépôt de	ts-Unis, §120 de tour de(s) ci-après et, dan revendications de ce demande américaine emier paragraphe de , je reconnais le dev e selon Titre 37 du 6 , toute information	bénéfice selon Titre 35 te(s) demande(s) amé- se la mesure où le sujet ette demande n'est pas e antérieure, de la façon e Titre 35 du Code des oir de divulguer l'infor- Code des Réglements e qui se présente entre eure et la date de dépôt ternationale PCT.	I hereby claim the benefit unde §120 of any United States a insofar as the subject matter application is not disclosed in cation in the manner provided 35, United States Code, §11 disclose material information and Federal Regulations, §1.56 filling date of the prior application and the prior application of the prior app	application(s) listed be r of each of the claim in the prior United State d by the first paragraph 2, I acknowledge the as defined in Title 37, which occurred betwation and the national	low and, is of this es appli- h of Title duty to Code of yeen the
(Application (No. de D		(Filing Date) (Date de Dépôt)	(Etat) (brevetée, pendante, abandonné)	(Status) (patented, pending, abandoned)	
(Application (No. de D		(Filing Date) (Date de Dépôt)	(Etat) (brevetée, pendante, abandonnée)	(Status) (patented, pending, abandoned)	

Je déclare par le présent acte que toutes mes déclarations, à ma connaissance, sont vraies et que toutes les déclarations faites à partir de renseignements ou de suppositions, sont tenues pour être vraies; de plus, toutes ces declarations ont été faites en sachant que de fausses déclarations volontaires u autres actes de même nature sont sanctionées par une amende ou un emprisonnement, ou les deux, selon la Section 1001, du Titre 18 de Code des Etats-Unis et que de selles déclarations délibérément fausses peuvent compromettre la validité de la demande ou du brevet délivré.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Declaration and Power of Attorney For Patent Application Declaration Pour Demandes de Brevets Avec Pouvoirs

French Language Declaration

En tant qu' inventeur nomme ci-après, Je déclare par le présent acte que:	As a below named inventor, I hereby declare that:
Mon nom, mon domicile, mon adresse postale, ma nationalité sont ceux qui figurent ci-après,	My residence, post office address and citizenship are as stated below next to my name,
Je déclare que je crois être l'inventeur original, premier et unique (si un seul nom figure sur le présent acte) ou un des co-inventeurs, originaux et premiers (si plusieurs noms figurent sur le present acte) du sujet revendiqué et pour liquel un brevet est demande sur la base de l'invention intitulée:	I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled MULTILUMEN CATHETER, PARTICULARLY
	FOR HEMODIALYSIS
dont la description (cocher la case correspondante)	the specification of which (check one)
est annexée au présent acte.	is attached hereto.
a été déposée	was filed on as
Numéro de série de la demande	Application Serial No.
et modifiée le(si approprié)	and was amended on(if applicable)
Je déclare par le présent acte avoir examiné et compris le contenu de la description identifiée ci-dessus, revendications y compris, et le cas échéant telle que modifiée par l'amendment cité plus haut.	I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.
Je reconnais le devoir de divulguer l'information qui est en rapport avec l'examen de cette demande selon Titre 37 du Code des Reglements Fédéraux §1.56 .	I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56.
Pogo 1	

		NT (DECLARATION) C 9(f) and 1.27(b))		
independent reduced fee to the Pate	inventor as de s under section nt and Trademan	I hereby declare efined in 37 CFR 1. 44(a) and (b) of k Office with rega	9(c) for purpos Title 35, Unite Id to the inves	ses of paying ed States Code,
obligation rights in t independent invention,	under contract he invention to inventor under or to any conce	ed, conveyed or li or law to assign, o any person who co 37 CFR 1.9(c) if ern which would not i) or a nonprofit o	grant, convey ould not be class that person had qualify as a	or license, any ssified as an in made the small business
conveyed, o	r licensed or a	ganization to which m under an obligat license any rights	ion under conti	ract or law to
		person, concern, , concerns, or org		
concern or o	arate verified organization ha mall entities.	statements are required rights to the (37 CFR 1.27)	uired from each invention aver	n named person, rring to their
FULL NAME	POURCHEZ Th	ie ¢ ry		
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Applicant or Patentee: POURCHEZ Thierry eAttorney's Serial or Patent No: Docket No. Filed or Issued: For: MULTILUMEN CATHETER PARTICULARY FOR HEMODIALYSIS

